Section II. REMARKS

Amendment of Claims 1 and 19

Claims 1 and 19 have been amended herein to set forth such claims in better form for consideration and allowance by the Examiner.

Claim 1 has been amended to recite

"at least one thin gasket layer bonded to said filtration cassette on at least the main top and bottom surfaces thereof..."

and claims 1 and 19 have been amended to recite

"wherein the gasket layer on each main top and bottom surfaces of the filtration cassette has openings therein communicating with inlet basin, outlet basin and permeate passage openings of the filtration cassette."

Such amendment is consistent with the disclosure in the application, e.g., see FIG. 1 and FIG. 1A, showing inlet basin, outlet basin and permeate passage openings in the gasket and associated cassette; see also FIG. 3 and FIG. 3A; as well as appertaining text in the specification, e.g., at page 17, lines 4-5 ("fully encapsulated by a gasket layer 2") and at page 21, lines 1-2 ("covered by two gasket layers 2 only on its upper and bottom surfaces").

Rejection of Claims 1-13, 16 and 19, and Traversal Thereof

In the March 26, 2003, Office Action, the Examiner rejected claims 1, 3-13, 16 and 19 under 35 U.S.C. §103(a) as being unpatentable over Kopf '930 in view of Demmer et al. and/or Karbachsch et al.

Such rejection is traversed in application to the claims 1, 3-13, 16 as amended herein.

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Reconsideration of the patentability of the amended pending claims is requested, in light of the ensuing remarks.

Patentable Distinction of Amended Claims 1, 3-13, 16 and 19 Over the Cited References

In his statement of rejection of the claims at page 2 of the March 26, 2003 Office Action, the Examiner has conceded that Kopf '930 lacks disclosure of the gasketing structure of the present claimed invention, but has pointed to Demmer et al.'s element 3 in FIG. 3 of such reference, and to element 90 in FIG. 2 of Karbachsch et al. as gasket layers, and contended that:

> **"it would have been obvious to have modified the cassette of Kopf so as to have included the gasket layer as suggested by Demmer et al and Karbachsch et al in order to provide fluid tight layer between the cassette and adjacent structure"** (page 2, March 26, 2003 Office Action)

Applicant vigorously disagrees.

Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination and suggesting the desirability of the combination. According to the Board in *Ex parte Obukowicz*, 27 U.S.P.Q. 2d 1063, 1065 (B.P.A.I. 1992):

> "In proceedings before the Patent and Trademark Office, the examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art....The examiner can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teaching of the references."

Viewed against this standard, the Examiner's contention of obviousness fails on logical grounds to present any basis for proper rejection of applicant's claims.

The Examiner has said that "it would have been obvious to have modified the cassette of Kopf so as to have included the gasket layer as suggested by Demmer et al and Karbachsch et al in order to provide fluid tight layer between the cassette and adjacent structure," BUT the Examiner in making such contention is positing the existence of a problem of leak-tightness in the cassette structure of Kopf that is nowhere evident **from the teachings of such reference**.

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In fact, Kopf contains extensive teachings of the use of gaskets in his disclosed cassette-based filter assemblies - see column 13, lines 51-53 ("a compressible gasket is disposed between the rigid endplate and a manifold plate of the filter"); FIG. 1 and column 13, lines 60-61 ("compressible end gaskets and end plates"); FIG. 8 and column 14, line 15 ("compressible end gasket"); FIG. 8A and column 14, line 17 ("compressible end gasket"); FIG. 10 and column 14, line 25 ("compressible end gaskets"); and FIG. 17 and column 14, lines 62-65 ("compressible resilient gasket, such as may be employed between a rigid endplate and a manifold plate of a filter assembly comprising a filtration cassette in accordance with the present invention") - and in no instance is there any teaching or suggestion of any problem of leakage or leak-tightness.

Quite to the contrary, Kopf teaches that the gasket arrangement disclosed in such primary reference is highly efficacious! The Examiner's attention is directed to Kopf at column 23, lines 10-13, reproduced below for ease of reference:

> **"The gasket 600 permits a "hard shell" filtration cassette, i.e., a filtration cassette comprising an outermost rigid endplate, to be efficiently sealingly mated to a manifold plate of a filter comprising the filtration cassette."** (emphasis added; column 23, lines 10-13 of Kopf)

Given that the gasket - explicitly and repeatedly taught by Kopf as a component of his filter assembly - is characterized by Kopf as providing efficient sealing, what motivation is there for one to reject such teaching and structure, in favor of an approach of at least partially encapsulating the cassette with a gasketing material that:

(i) involves increased material requirements - rather than cutting out a gasket from a sheet stock material, the molding, dipping, spraying, etc. variously required for forming an integral gasket are more material intensive, and involve higher levels of waste of the encapsulant medium than is involved in simple cutting of sheet stock;

(ii) is more labor/capital equipment intensive - see the illustrative example in the instant application, at pages 28 and 29 thereof, describing the representative formation of the integral gasket as including (1) formulation mixing of the gasketing material, (2) degassing the gasketing material in a vacuum oven, (3) application of an initial thin film of the gasketing material to the cassette, (4) fume hood drying, (5) positioning the cassette in a mold, (6) addition of further gasketing material to the mold, while avoiding bubble formation, and (7) curing of the molded gasket material on the cassette at constant temperature, vs. a simple cut-out of the gasket from sheet stock

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material to form the gasket configuration taught by Kopf (see gasket 600 shown in FIG. 17 of Kopf); and

(iii) requires substantially longer fabrication time - see again the illustrative example in the instant application, at pages 28 and 29 thereof, which involves lengthy (as regards time) steps, stated to include 30 minutes rotating/mixing, 30 minutes degassing, overnight drying (~ 12 hours), retention of the resin in the mold prior to curing for "about 6 to 10 hours" (instant application, page 28, line 18), and curing at ambient for "at least 12 hours" (instant application, page 29, lines 3-4) or elevated temperature for "about 3 hours or less" (instant application, page 29, line5), which totals to a duration of from about 21 hours to about 35 hours, depending on the specific sequence of steps, vs. a simple cut-out of the gasket from sheet stock material to form the gasket configuration taught by Kopf, e.g., by a near-instantaneous die cutting of a sheet of rubber (see gasket 600 shown in FIG. 17 of Kopf)?

There is thus no logic in adopting the approach hypothesized by the Examiner, and in the process discarding Kopf's express teachings of an "efficiently sealingly" effective gasketing structure, in favor of a substantially different and more difficult and costly approach.

Further, even apart from the foregoing, which alone is a compelling rebuttal of the rejection, there is no logical basis for the combination of Demmer et al. and/or Karbachsch with Kopf.

Kopf discloses a cross-flow filtration apparatus - see Kopf at column 1, lines 25-27:

> **"The invention [of the Kopf reference] further relates generally to cross-flow filters comprising a multiplicity of stacked filtration cassettes"**
> (emphasis added; Kopf, column 1, lines 25-27)

Consistent with the cross-flow character of the Kopf filtration apparatus, Kopf describes an assembly that is schematically shown in side elevation (exploded) view in FIG. 18 of the patent, as reproduced on the following page for ease of reference, wherein I is the inlet of the filtration apparatus, O is the outlet for filtered retentate, PT is the permeate port from which collected permeate is discharged from the filter assembly. In such assembly, G_1 and G_2 are the gaskets and FC is the filtration cassette.

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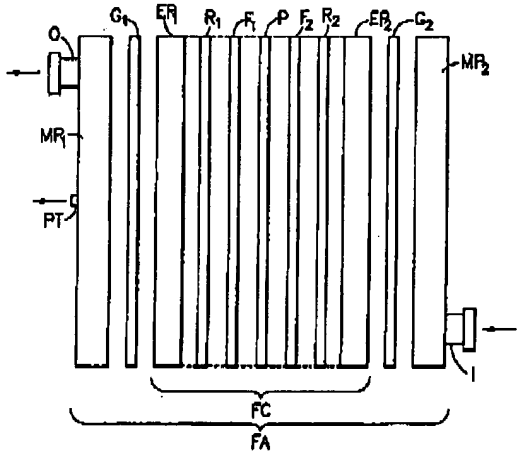

FIG.18

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This cross-flow filtration assembly of Kopf, wherein the gaskets G_1 and G_2 are on the respective end faces of the filter cassette, is to be contrasted with the dead-end filtration unit of Demmer et

Fig. 7

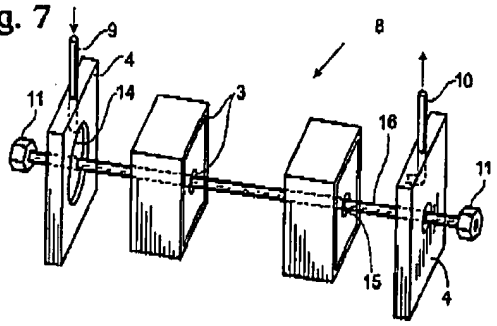
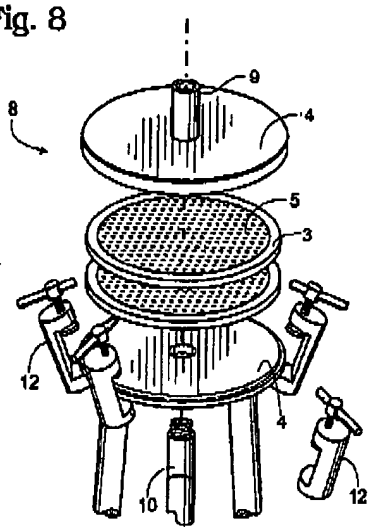


Fig. 8



al. (FIGS. 7 and 8 of the patent reproduced above for ease of reference), wherein the outer edges of the membrane filter sections 2 are sealed with an elastic sealant 3. In contrast to the Kopf filtration apparatus, wherein the end faces of the cassette are adjacent to gasket elements, the filter sections 2 of Demmer et al. CANNOT be faced with gaskets since the faces must remain open to the dead-end flow therethrough. There are no permeate/retentate flows out of the filtration unit of Demmer et al. - there is only feed in one end and permeate freed from separated substances out the other end (see Demmer et al., at column 4, lines 30-46). The separated material remains in and collects on the filter elements, so that the filtration unit must be

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selectively desorbed and eluted, as described at column 4, line 41, or else the filtration unit must be "opened" and "the filter cassettes removed" as described at column 4, lines 42-43 of Demmer et al.

Thus, Kopf seals the faces. Demmer et al. seals peripheral edges. Kopf is a cross-flow filter. Demmer is a dead-end filter. Neither teaches or suggests that there is a leakage problem or deficiency. There is therefore no logical derivative basis for the present invention in the teachings of Kopf and Demmer et al.

Alternatively, the Examiner has proposed to combine Kopf with Karbachsch. The sense of this combination is not understood, since again Karbachsch is a different filter configuration from that of Kopf. Karbachsch discloses an annular sealing ring that circumscribes a stacked filter unit assembly, as is shown for example in FIG. 11a of Karbachsch, reproduced for ease of reference below.

U.S. Patent [illegible] 5,225,080

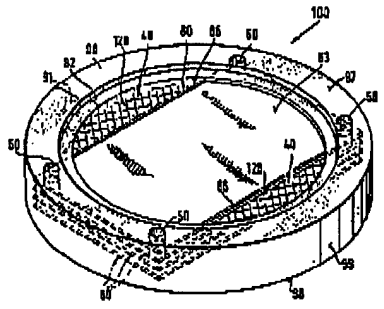

Fig. 11a

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The Karbachsch filtration module uses the annular sealing ring to form the "unfiltered material channels 40" (column 11, lines 20-21 of Karbachsch) as open areas between the inner surface of the annular sealing ring 90 and "the peripheral sections which are not embedded in the sealing ring 90" (column 10, lines 64-65 of Karbachsch). The stack of membranes 83 in Karbachsch at its end faces is merely embedded in the annular sealing ring at the corners of the stack.

The Karbachsch filtration module structure therefore is inconsistent with and fundamentally different from the filtration apparatus of Kopf. Kopf features gasket elements adjacent the end faces of the filter cassette. Karbachsch leaves such faces almost totally exposed (except for the corners embedded in the annular sealing ring 90.

If the Karbachsch annular sealing ring is arbitrarily extracted from the Karbachsch filtration module and arbitrarily inserted into the Kopf filtration apparatus (arbitrarily, because there is no basis in the teachings of either reference for such modification), then the resulting construction would be stripped of the gaskets that Kopf teaches (since the Examiner has proposed to modify the Kopf structure with the Karbachsch sealing ring ("gasket layer as suggested by ... Karbachsch et al"), and the sealing ring could only be deployed in the manner taught by Karbachsch (since there is no other way of deploying it), and the annular ring would still not be equivalent to or suggestive of applicant's claimed filtration structure including a

> **"gasket layer bonded to said filtration cassette <u>on at least the main top and bottom surfaces thereof</u> ..., <u>wherein the gasket layer on each main top and bottom surfaces of the filtration cassette has openings therein communicating with inlet basin, outlet basin and permeate passage openings of the filtration cassette</u>"**
>
> (claim 1, as amended)

The foregoing clearly shows the failure of the references cited, in evidencing any valid basis for combination. The Examiner in this respect is respectfully reminded that he <u>must explain with specificity</u> what areas of the references suggest the combination. See, e.g., *Ex parte Humphreys*, 24 U.S.P.Q.2d 1255, 1262 (B.P.A.I. 1992). This has not been done. Instead, the Examiner is merely reconstructing applicants' claimed invention in light of applicants' disclosure, but without any suggestive basis in the prior art references themselves. Such approach is improper and legally insufficient to establish any *prima facie* case of obviousness.

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The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990). Not only must the Examiner's rejection be specific as to how one of ordinary skill in the art would have found it obvious to combine references, the Examiner must explain with specificity what areas of the references suggest the combination. See, e.g., *Ex parte Humphreys*, 24 U.S.P.Q.2d 1255, 1262 (B.P.A.I. 1992).

It therefore is apparent that there is no derivative basis in either Demmer et al. or Karbachsch et al. for applicant's invention as claimed.

Apart from the foregoing, and as further extrinsic evidence of patentability of the applicant's claimed invention, it is pointed out that the filtration cassette arrangement involving separate gasket elements at end faces of the cassette is the standard approach of the art.

Set out on the following page is a digital photograph of a Millipore Pellicon 2 Cassette Filter Assembly, as commercially available from Millipore Corporation (Billerica, MA), which currently controls in excess of 70% of the filtration cassette market, showing the filter assembly product as sold with a filtration cassette unit, and two gasket elements, and appertaining instructions.

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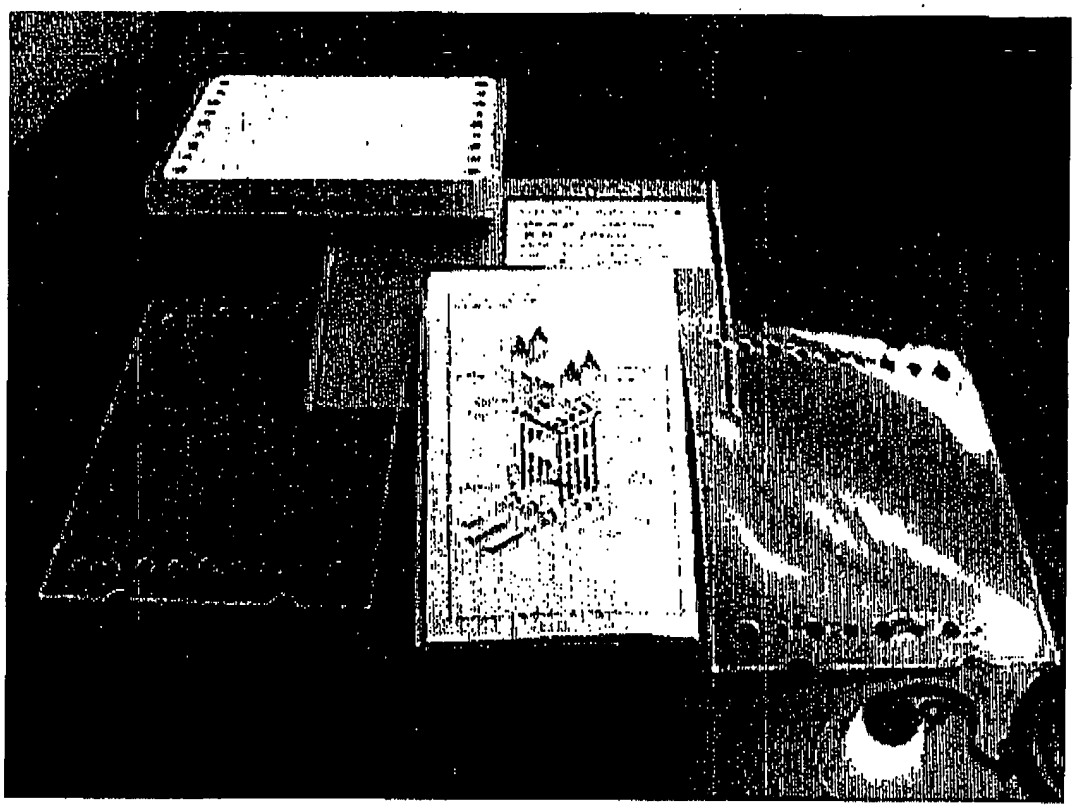

Enclosed in Appendix A of this Amendment is a Data Sheet published by Millipore Corporation for this Pellicon 2 filter product, which states on page 6, "Two gaskets are packed in the box with every Pellicon 2 filter."

This approach of utilizing separate gasket elements that are positioned between the end faces of a cassette and the manifold plate, as characteristic of the Millipore Pellicon product, and as disclosed in the Kopf patent, represents the current and conventional wisdom and approach of the art.

There is no basis in the Kopf patent or the secondary references of Demmer et al. and Karbachsch et al. for modifying the Kopf filtration apparatus in the manner hypothesized by the Examiner, and there are numerous reasons, discussed hereinabove, why one of skill in the art would reject such modification, as increasing the cost, manufacturing time requirement, and complexity of the filtration apparatus, in addition to the clear and unambiguous teaching by Kopf that

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> **"The gasket 600 permits a "hard shell" filtration cassette, i.e., a filtration cassette comprising an outermost rigid endplate, to be efficiently sealingly mated to a manifold plate of a filter comprising the filtration cassette."** (emphasis added; column 23, lines 10-13 of Kopf).

There is therefore an absence of any motivational or derivative basis in the art for the applicant's claimed filtration cassette apparatus.

Claim 1 accordingly is patentably distinguished over the cited combination of references, as are dependent claims 3-13 and 16 thereunder.

Claim 19 is patentably distinguished over the cited references on corresponding grounds (claim 19 reciting that the gasket layer "fully encapsulates said filtration cassette").

In addition to the arguments for patentability presented herein, applicant reaffirms the distinguishing remarks presented in the January 9, 2003 response, which are of record, and reinforce the patentable character of the invention as claimed.

The Examiner therefore is requested to reconsider, and on reconsideration to allow, the pending claims 1, 3-13, 16 and 19, as herein amended.

CONCLUSION

Claims 1, 3-13, 16 and 19 as amended herein, are now in form and condition for allowance. Favorable action therefore is requested.

If any issues remain outstanding, incident to the formal allowance of this application, the Examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss their resolution, in order that this application may be passed to issue at an early date.

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FAX RECEIVED
JUN 27 2003
GROUP 1700

Respectfully submitted,

Steven J. Hultquist
Reg. No. 28,021
Attorney for Applicant

INTELLECTUAL PROPERTY/
TECHNOLOGY LAW
P.O. Box 14329
Research Triangle Park, NC 27709
Phone: (919) 419-9350
Fax: (919) 419-9354
Attorney File No.: 2780-183

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Appendix A

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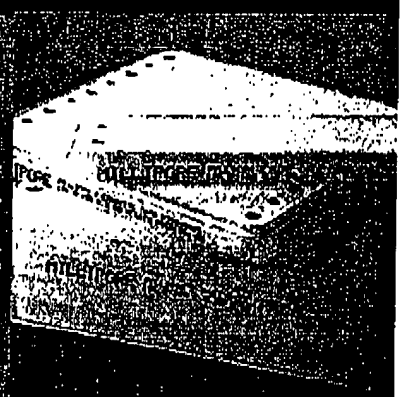
MILLIPORE

DATA SHEET



- Leading-edge void-free membranes to match virtually any separation challenge
- Short flow path for higher flux and higher resolution separation capability
- Choice of flow channel configuration providing process optimization capability
- Predictable, fast, scale-up
- True linear scalability from laboratory size modules to industrial assemblies for processing thousands of liters

Pellicon® 2 Filters and Holders

High-performance tangential flow filters for biopharmaceutical process development, scale-up/scale-down and concentration/ purification/cell harvesting applications

Typical Applications

Concentration, desalting or buffer exchange of:

- Protein solutions
- Polysaccharide solutions
- Virus suspensions

Harvest, washing or clarification of:

- Cell cultures and lysates
- Colloidal suspensions
- Viral cultures

Superior TFF Performance

For research, process development, scale-up and production, Pellicon 2 filters and holders offer the following benefits:

Consistent High Flux and High Product Recovery

Millipore's Biomax® polyethersulfone and Ultracel® PLC-composite regenerated cellulose membranes have void-free structures that guard against leakage of solutes through microdefects normally associated with voids beneath the thin skins of conventional UF membranes (Figures 1 and 2).

These void-free membranes more permeable, resulting in high-flux with equivalent or superior product retention (Figure 3). These void-free membranes provide the advantages of fast, high yield processing and smaller systems.

The long established Durapore® hydrophilic PVDF microfiltration membrane is well known for its exceptional combination of high flux, low protein binding and high product recoveries.

Figure 1. *Void-free Biomax 10 modified polyethersulfone membrane*

Figure 2. *Conventional 10 kD polyethersulfone membrane with sub-surface voids*

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Easy, Reliable Linear Scale-Up from th Lab to the Production Plant

Pellicon 2 Mini filters scale-up easily and reliably from the laboratory to the production plant (Figures 4 and 5). By ensuring every flow channel has the same length, height and turbulence promoter as well as flow direction and materials of construction, we maintain the same ultrafilter/microfilter performance at all scales. Thus, rapid and reliable translation of processes from lab to manufacturing scale is easily achieved.

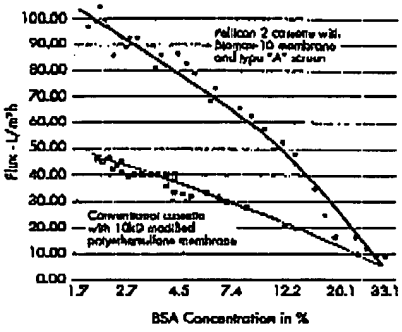
Linear Scale-Up

Mini filters (0.1 m^2/1.1 ft^2) and holders are designed for laboratory ultrafiltration/microfiltration of 100 mL to 10 L volumes, yet scale up linearly to Pellicon 2 Cassette (0.5 m^2/5.4 ft^2) and Maxi (2.5 m^2/26.9 ft^2) filters used in the pilot or manufacturing plant to process volumes from one liter to thousands of liters.

Thus, whether you operate 0.1 m^2 or 100 m^2 of installed area, every Pellicon 2 filter operates with the same pressure drop, flow velocity and concentration profile for true, rapid and simple linear scale-up.

Pellicon 2 Filters Proof of Performanc

Improved Flux



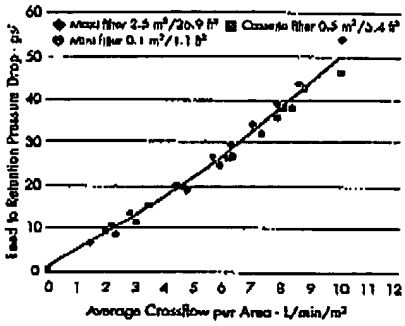
Feed pressure: 5.6 bar/80 psi
Retentate pressure: 2.1 bar/30 psi
Temperature: 10 – 13.5 °C
Initial volume 28 L
Final volume: 2 L

Conclusion

Pellicon 2 filters with Biomax membranes provide up to two-times the process flux of conventional cassettes resulting in faster processing and smaller systems.

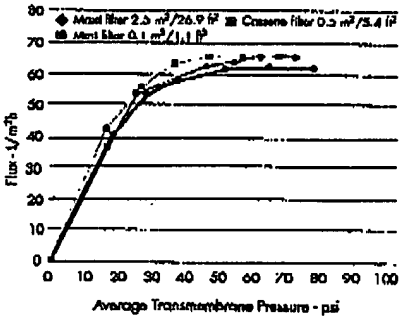
Figure 3. *Flux versus BSA concentration*

Linear Scalability



Temperature: 8 °C

Figure 4. *Feed to retentate pressure drop versus average crossflow on a 10% BSA solution*



Temperature: 8 °C
Feed to retentate pressure drop: 2.8 bar/40 psi

Conclusion

(Figures 4 and 5) Pellicon 2 family of cassette filters scale linearly from 0.1 to 0.5 to 2.5 m^2 (1.1 to 5.4 to 26.9 ft^2) sizes for rapid, accurate and safe process scale-up and transfer.

Figure 5. *Flux versus average transmembrane pressure on a 10% BSA solution.*

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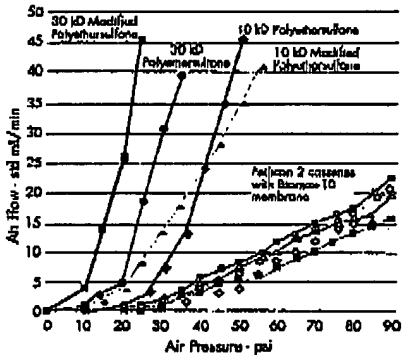
Improved Reliability



Conclusion
The void-free structure of Biomax membranes is demonstrated by low, linear air diffusion values. This performance ensures better process reliability and safety and better product retention for higher yields.

Figure 6. *Integrity test comparison-air flow through wetted cassettes*

Greater Process Reliability and Reproducibility

The combination of defect-free membranes with Millipore's highly reliable manufacturing processes, offers greater consistency of process parameters.

The high quality of Millipore's ultrafiltration membranes is further ensured by our pioneering multiple-solute mixed-dextran retention profile test. Unlike the single solute protein retention test, Millipore's retention profile test measures and ensures reproducible retention performance of our UF membranes over the entire range of molecular weights retained by the membrane, not just at one or two molecular weights.

Low Product Loss

Pellicon 2 filters have a low minimum working volume – as low as 175 mL of retentate volume per square meter of membrane area. This low retentate volume permits high concentration factors to be reached with low starting volumes and maximizes the recovery of small sample volumes.

To prevent product loss, Pellicon 2 filters are 100% tested in manufacturing to ensure that every filter is integral.

In addition, Biomax and Ultracel membranes are exposed to a new high-pressure integrity test that provides greater sensitivity. The integrity test procedure and specifications are supplied so users can confirm integrity at high pressure when the filter is installed (Figure 6).

Biocompatibility

All wetted parts have been tested and meet the requirements of th USP Class VI biological test for plastics.

Superior Filter Quality

Pellicon cassettes are subjected to a complete array of quality control release tests.

A Certificate of Quality is included with every cassette.

Each casette is identified with a unique serial number.

Validatable

Since 1973, Pellicon filters and systems have been successfully used for development and scale-up of processes for manufacturing injectable protein and polysaccharide drugs, in the serum fractionation, biotechnology, vaccine and pharmaceutical industries.

Pellicon 2 filters and systems were developed based upon Millipore's experience serving these applications, and are supported by an extensive Validation Support Data Package proving performance claims and demonstrating the suitability of these filters for drug manufacturing in validated processes. This package is available upon request.

Millipore can further assist your validation efforts through:

- Design and fabrication of standard and custom turnkey TFF systems for drug manufacturing facilities
- Installation and operational qualification services for these systems
- Validation support services for tangential flow filter use in drug manufacturing processes.
- Training on TFF process scale-up, optimization and development.

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A Choice of Feed Channel Screens

For optimal performance in a range of applications Pellicon 2 filters incorporate three types of feed-channel screens:

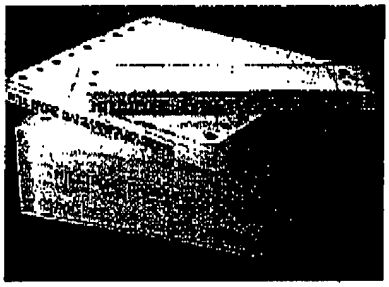
- *Type A screen (tight screen)* is optimized to operate Biomax membranes with maximum flux with low-viscosity solutions.
- *Type C screen (coarse screen)* is optimized to operate PLC series membranes with maximum flux. The Type C screen is also available with Biomax-50, 100, 300, 500 and Biomax 1000 membranes for concentration and diafiltration of viscous solutions.
- *Type V screen (open channel)* is optimized for very viscous solutions or solutions with higher levels of suspended solids.

Normalized Recirculation Rates

Parameter	Unit	Reduced ΔP			Typical ΔP		
Screen Type		A	C	V	A	C	V
Recirculation Rate	L/min/m²	4	9.5	19.6	9	14.6	33
Differential Pressure	bar/psi	0.7/10		0.2/3	1.4/20		0.4/6

Screen Selection Guidelines

Solution Type	Screen Type
Dilute protein solution or low viscosity solutions (Mab's, interferons)	A screen (tight screen)
Concentrated protein solutions or high viscosity solutions (IgG, biopolymers)	C screen (course screen)
High viscosity solutions (polysaccharides, certain microfiltration or clarification applications)	V screen (loose screen)



For More Detailed Information

Request literature number P17512 – Operation and Maintenance Guide for Pellicon Filters.

Specifications

Temperature Range

Mini, Cassette and Maxi:
4 to 50 °C

Maximum Forward Transmembrane Pressure

Device Size (m²)	Biomax	Ultracel
0.1	6.8 bar (100 psi) Max	6.8 bar (100 psi) Max
0.5	6.8 bar (100 psi) at 30 °C	3.4 bar (50 psi) at 30 °C
2.5	6.8 bar (100 psi) at 30 °C	3.4 bar (50 psi) at 30 °C

Maximum Reverse Transmembrane Pressure

Device Size (m²)	Biomax	Ultracel
0.1	0.33 bar (5 psi)	.33 bar (5 psi)
0.5	33 bar (5 psi)	.33 bar (5 psi)
2.5	33 bar (5 psi)	.33 bar (5 psi)

Prefiltration Required

Mini, Cassette and Maxi:
100 µm

Dimensions

Device	Width	Length	Thickness
Mini	5.6 cm	21 cm	1.5 cm (V screen-2.16 cm)
Cassette	17.8 cm	21 cm	1.5 cm (V screen-2.16 cm)
Maxi	17.8 cm	21 cm	7.6 cm (V screen-9.0 cm)

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Membrane Selection Guidelin

Membrane Type	Materials	Benefits
Biomax	Modified polyethersulfone	Highest flux ultrafiltration membrane
		Excellent chemical resistance
		Void-free structure for higher yield and reliability
Ultracel PLC	Regenerated cellulose	Extremely low protein binding hydrophilic membrane (ideal for protein solutions < 20 g/L)
	PLC membranes are composite membranes cast on a microporous substrate for defect-free membranes with superior adhesion.	Highest product recovery and improved performance with difficult to process streams (antifoams, lipids, protein transmission applications)
	Brings higher resolution, improved yields and superior back-pressure resistance	
Durapore	Hydrophilic PVDF	Very hydrophilic microporous membrane for cell harvest or clarification applications

Pellicon 2 Membrane Selection Chart

Approximate Molecular Weight (range of solutes retained >99%, kD)		Membrane	NMWL (kD) or Microns	Membrane Material	pH Range
High Flux Biomax Membranes – Void-free for Higher Yield and Reliability					
12 – 25	(growth factors, hormones)	Biomax-5	5	modified polyethersulfone	1 – 14
25 – 50	(growth factors, hormones)	Biomax-8	8	modified polyethersulfone	1 – 14
50 – 100	(albumin, hemoglobin)	Biomax-10	10	modified polyethersulfone	1 – 14
100 – 140	(enzymes)	Biomax-30	30	modified polyethersulfone	1 – 14
140 – 300	(IgG's)	Biomax-50	50	modified polyethersulfone	1 – 14
300 – 500	(small viruses and antigens)	Biomax-100	100	modified polyethersulfone	1 – 14
>500	(IgM's, large viruses)	Biomax-300	300	modified polyethersulfone	1 – 14
>0.03 µm	(large viruses, colloids, particulates)	Biomax-500	500	modified polyethersulfone	1 – 14
>0.03 µm	(large viruses, cells, colloids, particulates)	Biomax-1000	1000	modified polyethersulfone	1 – 14
Ultracel PLC Series – for High Recoveries					
8 – 18	(proinsulin, hematopoetic factors)	PLCCC	5	regenerated cellulose	2 – 13
18 – 60	(hemoglobin, enzymes)	PLCGC	10	regenerated cellulose	2 – 13
60 – 200	(monoclonal IgG's)	PLCTK	30	regenerated cellulose	2 – 13
200 – 500	(small viruses, viral antigens)	PLCHK	100	regenerated cellulose	2 – 13
>500	(large viruses, IgM's)	PLCMK	300	regenerated cellulose	2 – 13
>0.03 µm	(large viruses, cells, colloids, particulates)	PLCXK	1000	regenerated cellulose	2 – 13
Durapore Membranes – for Microporous Applications					
Clarify cell lysates and protein solutions, clarify viral cultures		VVPP	0.1 µm	hydrophilic PVDF	2 – 11
Harvest & wash colloidal suspensions, bacterial cells; clarify protein solutions and viral cultures		GVPP	0.22 µm	hydrophilic PVDF	2 – 11
Harvest & wash colloidal suspensions, cell & viral cultures, clarify protein solutions & viral cultures		HVMP	0.45 µm	hydrophilic PVDF	2 – 11
Harvest cell cultures or colloidal suspensions		DVPP	0.65 µm	hydrophilic PVDF	2 – 11

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Ordering Information

Pellicon 2 Filters

Membrane	Filters with A Screens (Tight Screen) 0.1 m²/1.1 ft²	0.5 m²/5.4 ft²	2.5 m²/26.. ft²	Filters with Type C Screens (Coarse Screen) 0.1 m²/1.1 ft²	0.5 m²/5.4 ft²	2.5 m²/26.9 ft²
Biomax Series – Modified Polyethersulfone						
Biomax 5	P2B0 05A 01	P2B0 05A 05	P2B0 05A 25	+	+	+
Biomax 8	P2B0 08A 01	P2B0 08A 05	P2B0 08A 25	+	+	+
Biomax 10	P2B0 10A 01	P2B0 10A 05	P2B0 10A 25	+	+	+
Biomax 30	P2B0 30A 01	P2B0 30A 05	P2B0 30A 25	+	+	+
Biomax 50	P2B0 50A 01	P2B0 50A 05	P2B0 50A 25	P2B0 50C 01	P2B0 50C 05	P2B0 50C 25
Biomax 100	P2B1 00A 01	P2B1 00A 05	P2B1 00A 25	P2B1 00C 01	P2B1 00C 05	P2B1 00C 25
Biomax 300	+	+	+	P2B3 00C 01	P2B3 00C 05	P2B3 00C 25
Biomax 500	+	+	+	P2B5 00C 01	P2B5 00C 05	P2B5 00C 25
Biomax 1000	+	+	+	P2B0 1MC 01	P2B0 1MC 05	P2B0 1MC 25
Ultracel PLC Series – Regenerated Cellulose, Composite Construction						
5 kD	NA	NA	NA	P2C0 05C 01	P2C0 05C 05	P2C0 05C 25
10 kD	NA	NA	NA	P2C0 10C 01	P2C0 10C 05	P2C0 10C 25
30 kD	NA	NA	NA	P2C0 30C 01	P2C0 30C 05	P2C0 30C 25
100 kD	NA	NA	NA	P2C1 00C 01	P2C1 00C 05	P2C1 00C 25
300 kD	NA	NA	NA	P2C3 00C 01	P2C3 00C 05	P2C3 00C 25
1000 kD	NA	NA	NA	P2C0 1MC 01	P2C0 1MC 05	P2C0 1MC 25
Durapore – Hydrophilic PVDF						
0.1 µm	+	+	+	P2VV PPC 01	P2VV PPC 05	P2VV PPC 25
0.22 µm	+	+	+	P2GV PPC 01	P2GV PPC 05	P2GV PPC 25
0.45 µm	+	+	+	P2HV MPC 01	P2HV MPC 05	P2HV MPC 25
0.65 µm	+	+	+	P2DV PPC 01	P2DV PPC 05	P2DV PPC 25

Each Pellicon filter is packed one per box and includes Operating Instructions. A Certificate of Quality is included in every box.
Silicone intercassette gaskets are required for use with Pellicon 2 filters. Two gaskets are packed in the box with every Pellicon 2 filter.

\+ = On request (custom order)
NA = not available

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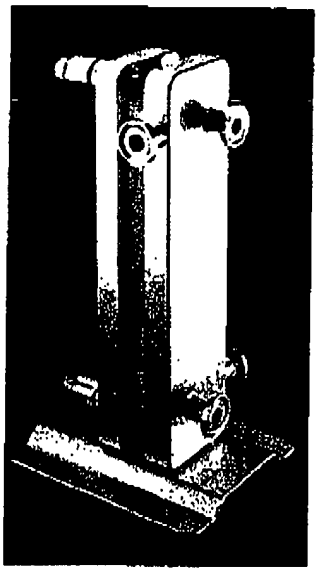
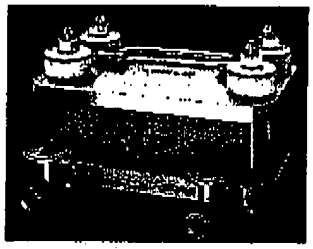
Filters with V Screens (Loose Screen)		
0.1 m²/1.1 ft²	0.5 m²/5.4 ft²	2.0 m²/21.5 ft²
P2B0 05V 01	P2B0 05V 05	P2B0 05V 20
P2B0 08V 01	P2B0 08V 05	P2B0 08V 20
P2B0 10V 01	P2B0 10V 05	P2B0 10V 20
P2B0 30V 01	P2B0 30V 05	P2B0 30V 20
P2B0 50V 01	P2B0 50V 05	P2B0 50V 20
P2B 100V 01	P2B1 00V 05	P2B1 00V 20
P2B3 00V 01	P2B3 00V 05	P2B3 00V 20
P2B5 00V 01	P2B5 00V 05	P2B5 00V 20
P2B0 1MV 01	P2B0 1MV 05	P2B0 1MV 20
P2C0 05V 01	P2C005V 05	P2C0 05V 20
P2C0 10V 01	P2C0 10V 05	P2C0 10V 20
P2C0 30V 01	P2C0 30V 05	P2C0 30V 20
P2C1 00V 01	P2C1 00V 05	P2C1 00V 20
P2C3 00V 01	P2C3 00V 05	P2C3 00V 20
P2C0 1MV 01	P2C0 1MV 05	P2C01MV 20
P2VV PPV 01	P2VV PPV 05	P2VV PPV 20
P2GV PPV 01	P2GV PPV 05	P2GV PPV 20
P2HV MPV 01	P2HV MPV 05	P2HV MPV 20
P2DV PPV 01	P2DV PPV 05	P2DV PPV 20





Pellicon 2 Mini Holder

Pellicon 2 Mini holder operates one to three Mini filters in parallel for total areas of 0.1 to 0.3 m² (1.1 – 3.3 ft²). This sanitary holder is tightened with a small torque wrench to compress the filters between a manifold plate that conveys fluids in and out of the filters and an end plate that seals the filters together. The Mini holder is designed for process development and small volume pharmaceutical manufacturing.

Materials of Construction

Manifold and End Plates:
316 L stainless steel

Base, Tie Rods, Spacers and Washers:
304 stainless steel

Feet:
Thermoplastic rubber

Gaskets:
Silicone

Nuts:
Silicone bronze

Separator Plates

An optional separator plate allows processing simultaneously with up to three 0.1 m²/1.1 ft² cassettes to determine the best molecular weight cut-off in a single study on the same feed material.

Connections

All manifold connections are standard ½-inch sanitary clamp type.

Operating Parameters

Temperature Range:
4 to 50 °C. The Mini holder can be autoclaved without filters installed. The filters themselves cannot be autoclaved.

Maximum Pressure:
6.8 bar

Dimensions

Height: 260 mm; *Width:* 114 mm

Length: 140 mm; *Weight:* 5 kg

Holder Manifold Volume:

Feed plus retentate: 5.3 mL

Permeate: 6.4 mL

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Stainless Steel Pellicon Holder XX42P0080

The stainless steel Pellicon filter holder, designed for sanitary applications, can be used alone or to expand existing cassette ultrafiltration (CUF) systems or to replace existing holders.

It requires only to be connected to an existing sanitary pump and piping for tangential flow microporous filtration or ultrafiltration.

It can accomodate up to 5 m²/55 ft² filter area as shipped with long tie rods or 0.5 to 2.5 m² (5.4 – 26.9 ft²) with accessory short tie rods.

Materials of Construction

Wetted Surfaces:
316 L stainless steel

Non-wetted Surfaces:
Silicon bronze nuts

Dimensions

Length: 28 cm; *Width:* 19 cm

Height: 25 cm

Operating Parameters

Operating Temperature Range:
4 to 50 °C. The Pellicon holder can be autoclaved without pressure gauges and filters; holder with gauges cannot be steamed. Pellicon filters cannot be steamed or autoclaved.

Connections

Sanitary ¾" TC connections; 1½" TC connections for gauges.

Shipping Weight

24 kg

Process-scale Pellicon Holder

The Pellicon Process-scale Holder is a unique innovation for production scale Pellicon systems. This holder, vertically mounted, can hold up to 80 m²/880 ft² of membrane area.

Benefits

- Extremely compact footprint
- Easy to change cassettes
- Easy to vent and fully drain
- Simple connections
- Up to 4 levels. Can be easily extended in levels for simple membrane area expansion
- Each level up to 20 m²/220 ft²
- Uses standard and Maxi Cassettes
- Can be adapted for series or parallel configurations
- Simplifies pipework connection
- Hydraulic closure systems are available for the stainless-steel Pellicon holder and the process-scale Pellicon holder. These systems are convenient, reliable and easy to use to enable rapid and repeatable loading operation and storage of Pellicon 2 cassettes.

Materials of Construction

Manifold segment, fitting blocks and end plate 316 L stainless steel; tie rods 304 and 304 L stainless steel.

Ordering Information

Pellicon 2 Filter Holders

Description	Catalogue No.
Pellicon 2 Mini filter holder	XX42 PMI NI
Pressure gauges One diaphragm-protected digital pressure gauge, 0 – 7 bar, ¾-inch fittings	XX42 PSG 01L
Pressure gauge adapters	XX42 PMO 01
Fitting kit Contains all tees, clamps, gaskets and a valve to connect tubing and pressure gauges to the Pellicon 2 Mini holder	XX42 PFK 01
Pellicon filter holder (for cassettes and Maxi filters)	XX42 P00 80
Pellicon 2 double thick gasket	PSSP 2XC 10
Pellicon Process-scale holder support and plate	XX42 SSP LT
Pellicon Process-scale holder	On request

To Place an Order or Receive Technical Assistance

For additional information call your nearest Millipore office:
In the U.S. and Canada, call toll-free 1-800-MILLIPORE (1-800-645-5476)
In the U.S., Canada and Puerto Rico, fax orders to 1-800-MILLIFX (1-800-645-5439)
Outside of North America contact your local office. To find the office nearest you visit www.millipore.com/offices.
Internet: www.millipore.com
Technical Service: www.millipore.com/techservice

MILLIPORE

A Typical Pellicon Production Processing System

Millipore supplies a range of standard and custom engineered systems. These systems can contain from 1 m²/11 ft² to several hunded m² of membrane area, with Clean-in-Place (CIP) or Steam-in-Place (SIP) integrated as appropriate. Systems can also be supplied with integrated process vessels in manual or fully automatic versions.

All systems are designed, engineered and manufactured in ISO® 9001 registered facilities, and are supplied with extensive validation data support packages.

Please contact us to discuss your specific application and process requirements.

Pellicon XL Devices for Process Development

For process development of volumes from 50 mL to 1 liter, Millipore offers Pellicon XL devices. This small volume TFF filter is designed for true scalability by providing the same flow path, channel length, and channel height as the Pellicon 2 cassettes. Based on proven TFF membrane technology, Pellicon XL devices ensure reliable, consistent and predictable performance.

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